Toward a National Framework for Conformity Assessment of Non-respiratory PPT

Personal Protective Technology Conformity Assessment Public Meeting

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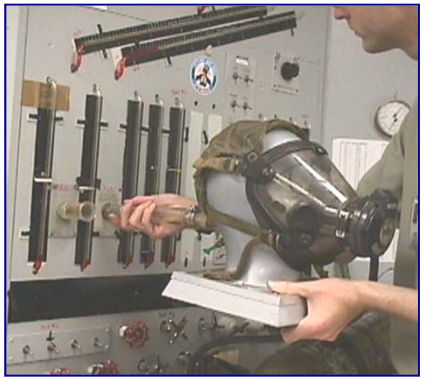
Overview

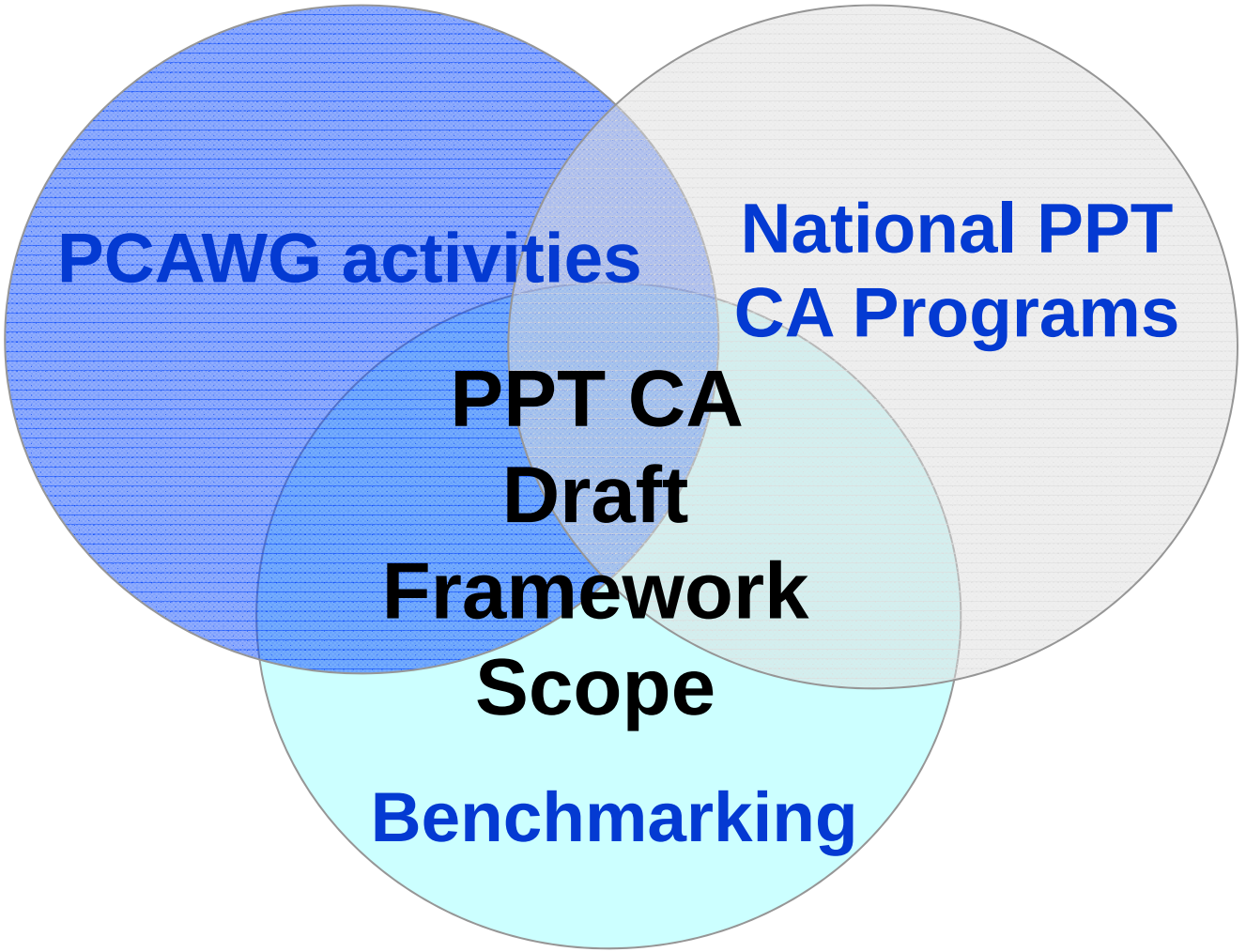
Basis for draft framework scope



Conformity assessment and market surveillance processes

Next steps

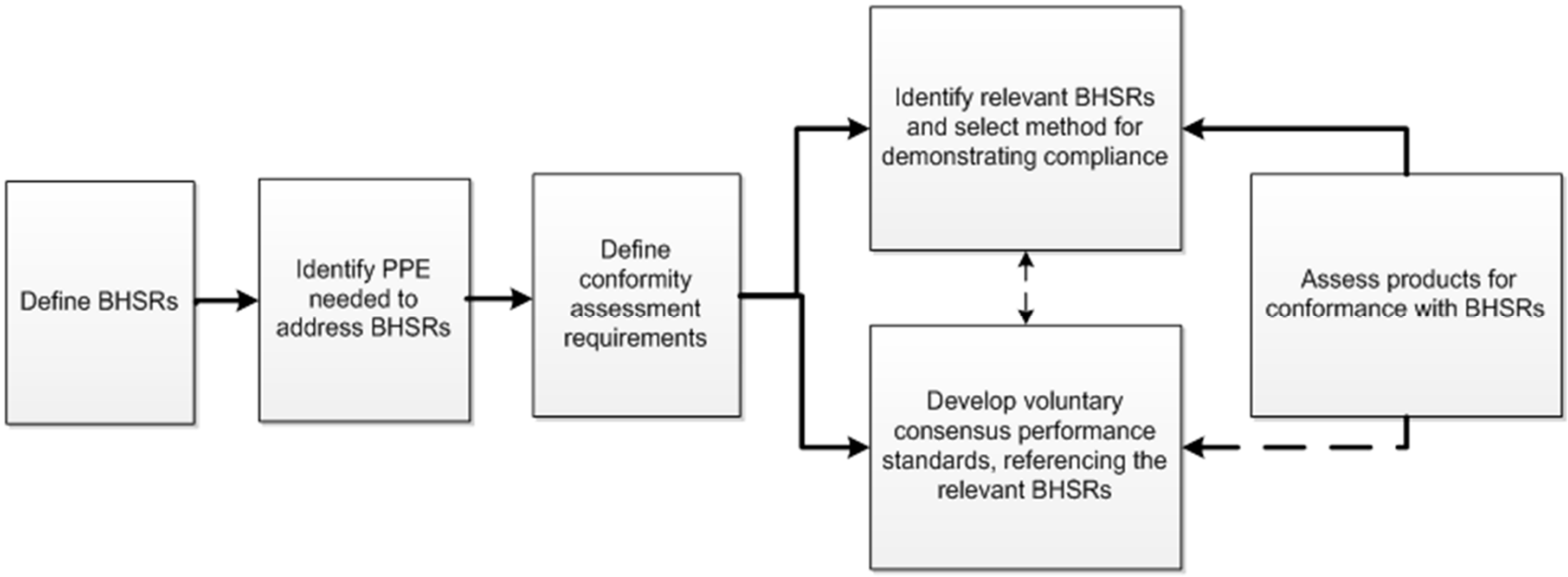
Multiple activities contributed to the draft framework scope



Questions for discussion today

1. Who defines the basic health and safety requirements (BHSRs) for your industry?
2. How should the BHSRs be established?
3. Who should address what PPE is needed to meet BHSRs?
4. Who determines the technical standards that demonstrate the BHSRs are met?
5. How are conformity assessment requirements linked to PPE types?

This is the process needed to further define the conformity assessment framework



BHSRs should be established as a basis of a national conformity assessment system

- BHSRs define the protection results to be attained
- BHSRs can be used to guide standards development
- Example – PPE to protect against mechanical vibration

PPE should be identified to address BHSRs

- Voluntary consensus standards should reference applicable BHSRs
- Address priority areas of research interest based on risk and national interest in areas that address the BHSR gaps
- Decisions about the technical approaches for achieving the relevant BHSRs for a product are made by the supplier

Conformity assessment should provide users confidence that product complies with the standard

- Conformity assessment activities should be based on ISO conformity assessment standards
- A federal authority is needed to provide oversight of non-respiratory occupational PPT CA
- Conformity with the BHSRs is the responsibility of the supplier

The appropriate CA components should be determined based on BHSRs and associated hazard

- Technical documentation
- Product testing
- Supplier's Declaration of Conformity (SDoC)
- Conformity marking
- Type-examination
- Third-party certification
- Quality system
- Post-market surveillance

Conformity assessment should be based on BHSRs representing tiered, hazard based approaches

- Hazards – corresponding to the BHSRs – should be placed in tiered categories
- Conformity assessment requirements should be assigned to each category of hazard.
- Requirements should be consistent with international standards and practices to facilitate trade

Example: OSHA Occupational Risk Pyramid for Pandemic Influenza
OSHA 3327-02N (2007)

Next steps to move the conformity assessment processes of the draft framework scope forward

- Determine approach to maintain the products and standards database
- Develop a systematic approach and strategy to documenting and disseminating information about PPE use with an emphasis on PPE use for high and medium risk workplace hazards
- Determine which hazards are medium to high risk
- Conduct an impact assessment regarding the draft framework scope

Market surveillance will provide information on field use by collecting data from many sources

Routine surveillance

Complaints about a product

Media reports

Authorities in other countries

Market surveillance guidelines and authorities

- A federal market surveillance authority should be established
- Market surveillance should follow the ISO standards.
- Market surveillance plans should be based on hazard and risk
- Plans should be monitored, evaluated & adapted as needed.
- An online, publicly accessible database of all third-party market surveillance bodies should be established

Accredited third-party market surveillance bodies should:

1. Inspect manufacturing facilities
2. Conduct documentary checks
3. Randomly select sample products, either onsite or from the open market
4. Make initial physical checks of the products
5. Conduct laboratory tests
6. Make assessments

Adverse event reporting system

- Provide PPT users and customers a vehicle for reporting PPT failures or requesting PPT evaluation
- Expand an existing reporting system to include PPT, e.g.:
  - CPSC's Publicly Available Consumer Product Safety Information Database (SaferProducts.gov)
  - FDA's Manufacturer and User Facility Device Experience Database (MAUDE), or
  - FDA's MedWatch Program
- The market surveillance authority should alert the public when actions have been taken against products not conforming

The market surveillance authority should be authorized to enforce corrective actions.

1. Official warnings and fines
2. Alerts to consumers
3. Sales bans
4. Product withdrawals
5. Product recalls

The market surveillance authority should be independently evaluated

- Evaluate from both an effectiveness and a cost/benefit perspective
- Third party market surveillance authorities should be required to provide data on output indicators

Surveillance data for market surveillance planning

Evidence for prioritizing surveillance projects includes:

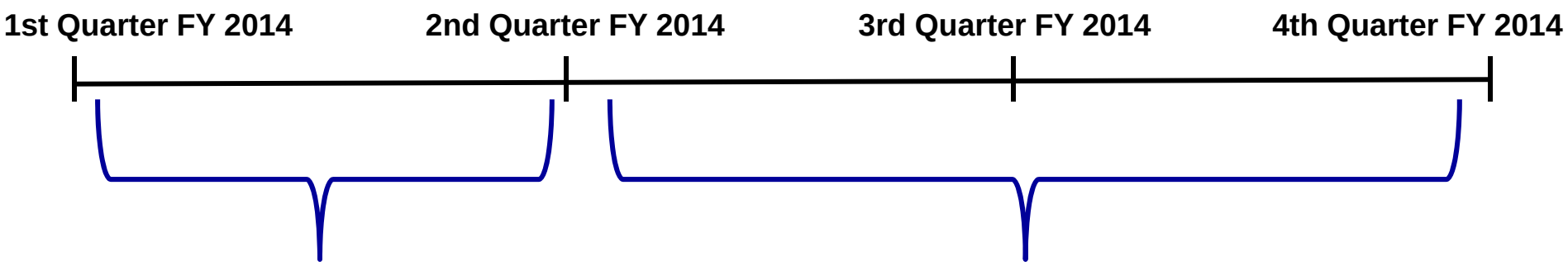
- Census of Fatal Occupational Injuries (CFOI)
- Survey of Occupational Injuries and Illnesses (SOII)
- MHSA's Mine Accident Injury and Illness database
- National Electronic Injury Surveillance System — Work Supplement (NEISS- WORK)
- OSHA's Data Initiative (ODI)
- Worker's Compensation data

Next steps to move the surveillance and database activities of the draft framework scope forward

- Expand existing data collection program(s) to include reports of unsafe PPT & PPT-related injuries and illnesses
- Develop registry of third-party conformity assessment and market surveillance bodies
- Explore expanding consumer alert system(s) to include PPT
- Develop data reporting requirements for third-party bodies to support monitoring & evaluation of the conformity assessment and market surveillance systems

Near-term activities

Oct 2013 — **Jul 2014**



Begin cost-benefit study of proposed CA market surveillance programs

Review docket comments received through December 1

Reconcile comments and submit framework for publication

Post updated framework scope

Conduct 2nd public meeting

Publish final report on CA framework

Continue implementing strategy

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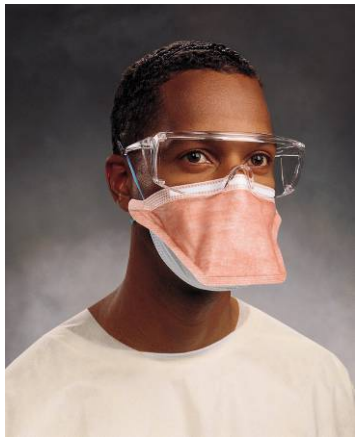
Quality Partnerships Enhance Worker Safety & Health

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Thank you

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